(3)

No. 90-45

IN THE

Supreme Court of the United States

OCTOBER TERM, 1990

HOFFMANN-LA ROCHE INC.,

Petitioner,

—v.—

UNITED STATES DISTRICT COURT FOR THE NORTHERN DISTRICT OF ALABAMA,

Respondent.

MOTION FOR LEAVE TO FILE BRIEF AND BRIEF OF *AMICUS CURIAE* AMERICAN MEDICAL ASSOCIATION IN SUPPORT OF HOFFMANN-LA ROCHE INC.'S PETITION FOR A WRIT OF CERTIORARI TO THE UNITED STATES COURT OF APPEALS FOR THE ELEVENTH CIRCUIT

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Pursuant to Rule 37.2 of the Rules of this Court, the American Medical Association respectfully moves the Court for leave to file a brief amicus curiae in the above entitled case. Counsel for Respondent Real Parties in Interest declined on July 2, 1990 to consent to filing; the Petitioner has granted its consent.

The American Medical Association ("AMA") is the nation's largest medical association. Its membership includes more than 255,000 physicians and medical students. Because many of its member physicians voluntarily submit adverse drug reaction reports in confidence to pharmaceutical manufacturers and the United States Food and Drug Administra-

tion ("FDA"), the AMA's interest is directly implicated in this case.

The AMA believes that the Eleventh Circuit's sanctioning of the district court's order compelling the disclosure of the identity of scores of physicians who voluntarily submitted adverse drug experience reports in confidence to Petitioner Hoffmann-La Roche Inc. was in error. The broad effect of this order will be to seriously deter physicians' voluntary compliance with the FDA's adverse drug experience reporting system. The AMA believes that the attached amicus brief will be of assistance to this Court in addressing this issue which is raised in Hoffmann-La Roche Inc.'s Petition for a Writ of Certiorari.

For the foregoing reasons the motion of the American Medical Association to file a brief amicus curiae in support of Hoffmann-La Roche Inc.'s Petition for a Writ of Certiorari to the United States Court of Appeals for the Eleventh Circuit should be granted.

Respectfully submitted,

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QUESTION PRESENTED

Whether public health and safety will be seriously jeopardized by the compelled disclosure of the identity of physicians who voluntarily and in confidence submit adverse drug experience reports to pharmaceutical manufacturers and the United States Food and Drug Administration.

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INTEREST OF *AMICUS CURIAE*

The American Medical Association ("AMA") is the nation's largest medical association. Its membership includes more than 285,000 physicians and medical students. Since its inception in 1847, the AMA has been dedicated to protecting the public welfare by maintaining the highest professional standards and promoting quality medical care.

The AMA regularly advocates policy positions on public issues that affect the quality and availability of medical care. In recent years, the AMA has become concerned that rapidly growing administrative burdens on physicians are contributing to the increasing cost of medical services and distracting the attention of physicians from the actual delivery of care. The source of administrative burdens include: (i) voluminous requests for information from third party payors of health care services; (ii) governmental regulations; and (iii) the need to prepare for and respond to litigation, including litigation in which a physician is not a party but is used as a source of information.

Among physicians, the growing administrative burden is known colloquially as the "hassle factor." For obvious reasons, physicians tend to avoid activities which will increase the hassle factor in their practices when it is possible to do so. The hassle factor increases their costs, takes time away from patients, is not paid for, and is not gratifying to do.

The voluntary adverse drug reporting program of the federal Food and Drug Administration ("FDA") is an activity which is important to maintaining and enhancing the quality of medicine. The decision below will subject physicians who participate in the program to routine, ongoing and unending discovery by plaintiffs who are not their patients. That result will have a debilitating effect on physician participation in the program, and the public health would thereby suffer.

ARGUMENT

IF ALLOWED TO STAND, THE PANEL MAJORITY OPINION WILL SERIOUSLY JEOPARDIZE PUBLIC HEALTH AND SAFETY

Thousands of members of the AMA voluntarily submit confidential adverse drug experience reports ("ADRs") to the ("FDA") and to pharmaceutical manufacturers. Physicians are the front line of the ADR reporting system. They are the ones who first identify adverse drug experiences in patients and who then voluntarily submit this information to the pharmaceutical manufacturers and the FDA. In turn, the pharmaceutical manufacturers and the FDA rely upon these voluntary reports for investigation of adverse experiences, warnings to physicians, changes in prescribing information, and medical and scientific research, all of which are crucial to the safe use of these drugs. As Gerald A. Faich, M.D., M.P.H., then Director of the FDA's Office of Epidemiology and Biostatistics has observed, the FDA depends upon the information provided by ADRs as an "early warning so that disasters might be avoided." *See* Food & Drug Law Institute Meeting, Special Reporting Considerations for PMS Studies, and Foreign Reports at 3 (Nov. 4, 1987).

Under federal regulations, the identity of the reporting physicians is kept confidential. To ensure that physicians continue voluntarily to submit ADRs, it is necessary to maintain intact the current policy of non-disclosure of the physicians' identities. If physicians' identities were not kept confidential, there would be a tremendous disincentive for physicians to file the reports. Reporting physicians would be subject to contact and harassment by plaintiffs and their attorneys. Reduced reporting, in turn, reduces the effectiveness of the ADR reporting system and its concomitant value for ensuring public health and safety.

The panel's refusal to issue a writ of mandamus to correct a grievous error by the trial court thereby creates a serious risk to the public health and safety. In dissenting from the

panel decision, Judge Clark recognized that the district court wholly failed to consider the importance of keeping confidential the names of physicians who submit ADRs. Disclosure of physicians' names will seriously jeopardize the ADR reporting system and, in turn, public health and safety. This truism has been recognized not only by the FDA, but by numerous courts as well.

Harris v. Upjohn Company, 115 F.R.D. 191 (S.D. Ill. 1987), for example, is directly on point. In *Harris*, the defendant pharmaceutical manufacturer moved for reconsideration of the district court's order compelling disclosure of physicians' names in Adverse Reaction Reports and Drug Experience Reports in defendant's files. The court granted defendant's motion for reconsideration, holding that:

> A careful review of this case persuades the Court that the release of the names of physicians who communicated to [defendant] would be against public policy.

Id. at 192. In so holding, the Court specifically found that disclosure of physicians' names would deter physicians from providing ADRs, which in turn would deter efforts to conduct research in the medical and science community. *Id.* The Court also recognized that the policy of non-disclosure has explicitly been expressed in the Code of Federal Regulations. *Id.* These regulations provide that the names of physicians voluntarily submitting ADRs either to the FDA or to pharmaceutical manufacturers shall be kept confidential. *See* 21 C.F.R. § 20.112; 21 C.F.R. § 314.80(h).

As the *Harris* Court recognized, physicians would be extremely reluctant to submit such reports voluntarily if their names were not kept confidential. Physicians are in the business of treating the sick, not of being compelled to serve as witnesses in lawsuits not involving their patients. Voluntary submission of ADRs by physicians would virtually dry up if the identity of the physicians submitting them were routinely disclosed to plaintiffs in unrelated litigation. If the source of these submissions disappeared, valuable medical information would be lost and the public health and safety thereby jeop-

ardized. *See also Stahl v. Rhee*, 136 A.D.2d 539, 540, 523 N.Y.S.2d 159, 161 (2d Dep't 1988) ("drug experience reports are an important component of the Food and Drug Administration's voluntary reporting procedure, and revealing such identities could compromise this beneficial endeavor"); *Wesley v. Rye*, 490 So.2d 272, 272 (La.), *reh'g denied*, 492 So.2d 1210 (1986) (names of physicians on drug experience reports ordered deleted).

The error of the district court's order is further illustrated by the fact that the district court completely failed to consider any reasonable alternatives to its order. For example, in *Newsom v. Breon Laboratories, Inc.*, 709 S.W.2d 559, 560 (Tenn. 1986), the court recognized both the reporting physicians' expectation that their identities would be kept in confidence and the importance of confidentiality in promoting the "effectiveness" of the ADR system. *Id.* at 560. Balancing these interests against that of the party seeking disclosure of the physicians' identities, the court decided to allow a *limited* number of reporting physicians' identities to be disclosed to plaintiffs under strictly controlled conditions. *Id.* Plaintiffs were allowed to select the 12 out of over 300 ADRs in which they were most interested in learning of the reporting physicians' identities. The names and addresses of these physicians were then to be kept under seal and revealed only to plaintiff's attorney of record. In addition, the clerk of the court was to notify the 12 physicians selected that defendants had been ordered to reveal their identities to plaintiffs but that their names would not be revealed to others without their respective permission. *Id.*

Such a reasonable alternative to wholesale disclosure was in fact the course of action recommended for the instant case by Judge Clark in his dissent from the Eleventh Circuit's summary denial of Hoffmann-La Roche Inc.'s petition for a writ of mandamus. Given the important public health and safety considerations discussed above, at a minimum such a reasonable compromise would appear to warrant consideration by the district court upon remand of this case.

CONCLUSION

It is the promise of confidentiality in exchange for voluntary submission of ADRs that keeps the ADR reporting system operative and provides significant, recognized benefits for public health and safety. Because this promise has been seriously jeopardized by the decision of the panel majority, this Court should summarily reverse the decision of the Eleventh Circuit.

Amicus thus supports Hoffmann-La Roche Inc.'s Petition for a Writ of Certiorari to the United States Court of Appeals for the Eleventh Circuit.

Respectfully submitted,

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